UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,632	05/14/2001	Robert E. Reiter	30435.69USD4	2142

26941 7590 10/14/2003

MANDEL & ADRIANO
55 SOUTH LAKE AVENUE
SUITE 710
PASADENA, CA 91101

EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	PAPER NUMBER
1642	24

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,632	REITER ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *87 and 89-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *87,89-96 and 100-103* is/are rejected.

7)☒ Claim(s) *97-99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claim 88 has been canceled and claims 94-103 have been added.

2. Claims 87, 89-103 are pending and under examination.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

4. The following Office Action contains NEW GROUNDS of rejection.

5. It is acknowledged that the substitute specification has been entered.

Claim Objection

6. Claim 96 is objected to because of a typographical error in the term "proteinand" in line two.

Rejections Withdrawn

7. The rejection of claim 88 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the canceled claim.

Response to Arguments

8. The rejection of claims 87, 89-93 and newly added claims 94-103 under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 1-3 of U.S. Patent No. 6,258,939 in view of Laus et al (U.S. Patent 6,194,152) is maintained. The rejection applies to claims 94-103 because it would be obvious that the antibody binding to 2-50, would also bind to residues in 18-98 and 21-99 of SEQ ID NO:2 and have the claimed properties as recited in claim 96.

The response filed 8/24/03 has been carefully considured but is deemed not to be persuasive. The response states that should the pending claims be found patentable, applicants will submit a terminal disclaimer (see page 8 of response). In response to this argument, no terminal disclaimer has been filed and as such the rejection stands.

9. The rejection of claims 87, 90, 92 under 35 U.S.C. 102(e) as being anticipated by Au-Young (U.S. Patent 5,856,136, filed 7/96) is maintained.

The response filed 8/24/03 has been carefully considured but is deemed not to be persuasive. The response states the legal standards for novelty, enablement, and non-obviousness (see pages 9-15 of response). In response to this argument, the examiner is well aware of the legal standards. The response further states that the Au-Young reference is not enabled and that Au-Young does no more than describe a gene with no function and the reference contains insufficient description and disclosure such that a person skill in the art would understand that Au-Young possessed a gene that encodes SCAH-2 protein or the protein or antibodies to the protein and Au-Young shows no deposit of biological materials to remedy the uncertainty of the nucleic acid

(see page 15 of response). In response to this argument, a US Patent is presumed to be valid and enabled. In addition it appears that the response is arguing that Au-Young did not describe the protein or antibodies or that the antibodies were never produced. In response to this argument, applicants are directed to In re Sivaramakrishnan, 213 USPQ 441 (CCPA 1982) which clearly discusses that a reference that may not have actually reduced specific mixture to practice has no bearing on whether the mixture is described in printed publication under 102(b). Thus, anticipation is anticipation and the prior art does not have to reduce it to practice. In addition, Au-Young discloses a protein sequence that is identical to SEQ ID NO:2 of the instant application (one amino acid at position at position 94 is indicated in Au-Young as XXX which when compared to the nucleic acid is in the IUPAC system is either C or G and this codon encodes ALA which is at position 94 in SEQ ID NO:2 of the instant application). Thus no deposit would be required because the amino acid sequence is disclosed. In addition it was well known at the time of the claimed invention to make antibodies to a protein and as such antibodies to SEQ ID NO:2 of Au-Young would bind to SEQ ID NO:2 of the instant application.

The response further states that without a definitive nucleic acid sequence of the expressed SCAH-2 protein, it is not possible for one of ordinary skill in the art to determine whether this protein is the same as applicants PSCA protein and Au-Young does not place one of skill in the art possession of SCAH-2 or antibodies directed to SCAH-2 (see page 16 of response). In response to this argument, the nucleic acid is not relevant because Au-Young teach the protein sequence, SEQ ID NO:2, which gives

one of ordinary skill the protein and as such one skilled in the art can produce antibodies to the protein which would bind to applicants SEQ ID NO:2.

The response further states that the SCAH-2 nucleic acid of Au-Young is derived from six overlapping fragments from two tissues and the fragments could have sequencing errors and the assembled gene could be a spliced into a variant gene and it may not be a gene at all but a pseudogene (see page 17 of response). The response further states that SEQ ID NO:4 of Au-Young is incomplete and has several unknown nucleic acids and SCAH-2 differs at both the nucleic acid and protein levels and Au-Young does not describe isolation of SCAH-2 from nature or a deposit of SCAH-2 sequence or SCAH-2 protein and Figure 2 of Au-Young provides the amino acid sequence but no open reading frame is identified and determining the correct amino acid sequence requires undue experimentation (see page 18-19 of response). In response to this argument, while the nucleic acid was assembled from overlapping clones the amino acid sequence is taught to be SEQ ID NO:2 and the protein is no different from applicants SEQ ID NO:2 and no undue experimentation would be required to obtain SEQ ID NO:2 because it is taught in Au-Young (when position 94 is ALA). In addition, again there is no need for a deposit because the sequence is disclosed.

The response further states that with respect to claims directed to antibodies that internalize and/or kill or are cytostatic to cells, claims 96-103, Au-Young disclosure cannot anticipate these claims 9see page 19 of response). In response to this argument, applicant is correct, the claims are not anticipated.

10. The rejection of claims 87-93 and newly submitted claims 94-95 under 35 U.S.C. 103(a) as being unpatentable over Au-Young et al (U.S. Patent 5,856,136, filed 7/96) as applied to claim87, 90, 92 above, and further in view of Green et al Nature Genetics 7:13-21, 1994) is maintained.

The response filed 8/24/03 has been carefully considured but is deemed not to be persuasive. The response states that Au-Young can not render the claimed invention obvious because there is no suggestion of applicants PSCA sequence or protein nor is there motivation to obtain compositions to detect or treat cancer and absence applicants sequences it would be hindsight to arrive at the invention and no protein of Au-Young was expressed and no antibodies were made and there is no function associated with Au-Young's protein (see page 20 of response). In response to this argument, the claims are directed to products not methods so therefore disclosure of cancer is irrelevant. Au-Young clearly teaches SEQ ID NO:2 of applicants protein and antibodies directed to the protein. Applicants are once again directed to In re Sivaramakrishnan, 213 USPQ 441 (CCPA 1982) which clearly discusses that a reference that may not have actually reduced specific mixture to practice has no bearing on whether the mixture is described in printed publication under 102(b). In addition, Au-Young teach that the antibodies can be used for diagnosis and the antibodies can be used to bind to tumor cells (see column 2, lines 44-52). The response further states that Au-Young can not provide motivation to prepare antibodies to PSCA that require internalize or kill or are cytostatic to cells (claims 96-103). In response to this argument, these claims were not rejected.

The response further states that Au-Young and Green at best would suggest that an antigen be made to the expressed product of the nucleic acid sequence disclosed in Au-Young and the references fail to suggest a monoclonal antibody which binds SEQ ID NO:2 of PSCA (see pages 22-23 of response). In response to this argument, Au-Young teach antibodies to SEQ ID NO:2 which is identical to applicant's SEQ ID NO:2 and as such in combination with Green, renders the claims obvious.

The following are NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

11. Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 95 has been added to recite an antibody which specifically binds amino acids residues 21 through 99 of SEQ ID NO:2. the response filed 8/24/03 states that support can be found in Figure 3 and the figure legend to figure 3 on page 6, lines 18-23. The response has been carefully considured but is deemed not to be persuasive. Although Figure 3 and the legend describe a single sequence and a C terminal GPI anchoring sequence, there is no support for an antibody that specifically binds residues 21 through 99. Applicant is required to provide specific support for the limitation in the specification as originally filed or remove it from the claim.

12. Claim 96 and 100-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claim 96 has been amended to recite "reduces tumor burden". Support for the amendment is stated to be at several locations in the specification, however, the examiner did not find support at the recited locations. The specification describes reducing tumor volume (see pages 117-118) but does not mention "tumor burden". Applicant is required to provide specific support for the limitation in the specification as originally filed or remove it from the claim.

13. Claim 96 and 100-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 96 recites the phrase "reduces tumor burden" and the phrase is indefinite. Does the phrase mean reducing the number of tumors or reducing the size of the tumors or reducing the symptoms associated with a tumor such as fever, etc?

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

LARRY R. HELMS, PH.D
PRIMARY EXAMINER